When should research involving children as subjects be permitted? This difficult and pressing problem is often presented in the form of a dilemma: If we do research involving children as subjects, then we do so using individuals who cannot give informed consent. If we do not, then children as a group are denied many of the benefits of research including therapeutic advances, the possibility of good information about therapies, and the repudiation of dangerous and discredited therapies. Robert Levine shows how the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The National Commission) tried to find a morally defensible solution to the question of when children may be enrolled as subjects in research. They held that with appropriate review, safeguards, consent from guardians, and assent from the child, children may be enrolled if the study on balance holds out direct and appropriate benefit to them or if the study is not too risky. Levine served as a consultant to the National Commission and shows sympathy (which I share) for the solution proposed.

In this paper, I will focus on the central notion of this policy that children may be involved in many kinds of research if it is not too risky or if on balance it holds out appropriate benefits for them. I will argue that this policy relies on a poorly defined concept of minimal risk. Without a consensus on what this means, the general agreement about when children may be research subjects may be illusory; and some empirical evidence exists suggesting that people tailor their notion of minimal risk to fit preconceived ideas about what kinds of studies should be done. After discussing why a standard is needed, I will turn to the question of how the current definition of "minimal risk" is inadequate.

I. REJECTION OF TWO EXTREME VIEWS

It is necessary to clarify what kind of risk is acceptable for children's studies. Two positions that would allow us to avoid doing so are unacceptable. One such policy permits the same kind of research to be done on children as is done with adults no matter what the risk. This is unreasonable because
competent adults may be at liberty to consent to take risks for the sake of others or for their own personal gain when they cannot volunteer others for such risks. Since children do not have the authority or are not generally competent to give consent for risky studies that do not hold out benefit for them, this extreme position is rejected.

Another policy that avoids clarifying what kind of risk is acceptable for children’s studies does so because it permits only research that directly benefits the child, as in therapy. Although this position at first seems humane and reasonable, it would, as Shirkey and Levine point out, make children “therapeutic orphans” [11, 12, 14]. It is a flawed policy because it makes it difficult or impossible to conduct controlled testing of therapies for children. Consequently, children would either do without or be given inadequately tested therapies. Moreover, this policy prohibits all non-therapeutic studies, no matter how low the risk. It would even disallow collection and analysis of the growth and development data obtained during children’s routine examinations. Altogether, this policy would leave children as a group sorely neglected medically. Suppose, for example, a child at four years of age seems developmentally delayed. We might want to determine if he can stack blocks or ride a tricycle as well as most four-year-olds. Unless we test many four-year-olds, we have no way of knowing the norm. But testing normal four-year-olds to see how well they can stack blocks or ride a tricycle to determine such standards would be a non-therapeutic study. All non-therapeutic studies would be disallowed under this policy. Even if the four-year-olds had a wonderful time, we could not record the results if doing so would constitute research. Having a good time, or even uncertain future benefits to a group, does not transform research into therapy. To call something therapeutic, we need to show through testing that it is likely to be useful to treat a certain illness. (Of course, stacking blocks and biking might be shown to be therapeutic, but I suspect that this would be more likely for the typical harassed investigator than for the average four-year-old.)

Rejection of the two extremes, permitting the same sort of research on children as on adults and permitting no research that does not hold out the prospect of direct benefit to the child, leaves a wide middle ground. Thus, it is necessary to offer some uniform standard about risk assessment in children’s research in order to have a clear policy. After discussing why a uniform standard is important, I argue that the current, widely adopted standard is poor.